

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<u>SHIRLEY SAVERCOOL and DONALD SAVERCOOL,</u>	:	
Plaintiffs,	:	CIVIL ACTION NO. 1:13-cv-12583RWZ
v.	:	MDL No. 2419
SERVICES, SPECIALTY SURGERY CENTER, PLLC; KENNETH R. LISTER; and CALISHER AND ASSOCIATES INC.	:	Master Docket No. 1:13-md-2419-RWZ
<u>Defendants.</u>	:	Honorable Rya W. Zobel
	:	<u>DEMAND FOR JURY TRIAL</u>

**FIRST AMENDED SHORT FORM COMPLAINT
AGAINST UNAFFILIATED DEFENDANTS**

Plaintiffs Shirley Savercool and Donald Savercool, against Defendants, allege as follows:

FIRST COUNT

1. Pursuant to MDL Order No. 7, entered in In Re: New England Compounding Pharmacy, Inc. Products liability Litigation, Master Docket No. 1:13-md-2419-RWZ, the undersigned counsel hereby submit this Short Form Complaint and Jury Demand against Defendants, and adopt and incorporate by reference the allegations in Plaintiffs' Master Complaint, with attachments, and any and all amendments thereto.

2. Plaintiff Shirley Savercool is a resident of the State of Tennessee.

3. Plaintiff Shirley Savercool brings this action:

☒ On behalf of herself.

☐ As the representative of _____, who is a living person.

☐ As the Administrator, Administrator ad Prosequendum, or other representative of the Estate of _____ (hereinafter “Decedent”), who died on _____.

4. Additionally, Plaintiff Donald Savercool, is the:

☒ Spouse

☐ Child/Children

☐ Other (Set forth) _____

of Shirley Savercool, is a resident of the State of Tennessee, and is hereby named as an additional plaintiff, and claims damages.

5. Plaintiff(s) assert(s) that Plaintiff Shirley Savercool was administered New England Compounding Pharmacy, Inc. (“NECC”) drug methylprednisolone acetate (hereinafter referred to as “NECC drug”), causing injuries and damages.

6. The aforesaid administration of the NECC drug occurred on September 13, 2012, by Kenneth R. Lister, M.D., at Specialty Surgery Center, PLLC (“Specialty Surgery Center”), located in Crossville, Tennessee.

7. Kenneth R. Lister, M.D., and Specialty Surgery Center and Calisher and Associates, are hereinafter collectively referred to as “Clinic Related Defendants.”

8. Plaintiff(s) adopt(s) and incorporate by reference the following Causes of Action asserted against Defendants in the Amended Master Complaint:

☐ COUNT II: NEGLIGENCE AND GROSS NEGLIGENCE (Against UniFirst)

☒ COUNT III: NEGLIGENCE AND GROSS NEGLIGENCE (Against Clinic Related Defendants)

- ☐ COUNT IV: VIOLATION OF CONSUMER PROTECTION STATUTES
(Against Clinic Related Defendants)

Plaintiff(s) allege violation of the following consumer protection statute(s): [List statutes. Note that N.J.S.A. 56:8-1 *et seq.* was inadvertently omitted from the Master Complaint]

- ☐ COUNT VI: VIOLATION OF M.G.L. C. 93A (Against UniFirst)
- ☐ COUNT VII: BATTERY (Against Clinic Related Defendants)
- ☒ COUNT VIII: FAILURE TO WARN (Against Clinic Related Defendants)
- ☒ COUNT IX: TENNESSEE PRODUCT LIABILITY CLAIMS (Against Specialty Surgery Center)
- ☐ COUNT X: AGENCY (Against Clinic Related Defendants)
- ☐ COUNT XI: CIVIL CONSPIRACY (Against Clinic Related Defendants)
- ☐ COUNT XII: WRONGFUL DEATH PUNITIVE DAMAGES (Against UniFirst and Clinic Related Defendants)
- ☒ COUNT XIII: LOSS OF CONSORTIUM (Against Clinic Related Defendants)
- ☒ COUNT XIV: PUNITIVE DAMAGES (Against Clinic Related Defendants)

9. Plaintiff(s) complied with all applicable state law pre-suit requirements for filing this litigation required under Tenn. Code Ann. §§ 29-26-121 (Written Notice of Claim) and 29-26-122 (certificates of good faith). That compliance is demonstrated by Exhibit A1 and A2, the affidavit showing the written notice of claim as required by Tenn. Code Ann. § 29-26-121, and Exhibit B, which is certificate of good faith, required by Tenn. Code Ann. § 29-26-122. Exhibit A1 and A2 and Exhibit B are expressly incorporated by reference herein.

10. Plaintiff(s) have sent or served the pre-suit notice or demand requirements necessary to bring the claims set forth below, as required under M.G.L. C. 93A. Plaintiff(s) do not now assert but will seek leave to amend to assert the following claims promptly after the time period for giving notice has expired: VIOLATION OF M.G.L. C. 93A (as set forth in Count VI

of the Master Complaint).

11. Plaintiff Shirley Savercool suffered the following injuries as a result of the administration of NECC's drug: Shirley Savercool contracted fungal meningitis, the effects of which she is still suffering. Shirley Savercool was severely ill. Shirley Savercool has experienced extreme physical pain and mental suffering. She continues to suffer as a result of the Defendants' negligent misconduct, acts, and omissions.

12. Plaintiff Shirley Savercool suffered the following damages as a result of the administration of NECC's drug(s): severe pain and suffering, mental anguish, disability, emotional distress, past and future medical care and treatment, increased living and support expenses, loss of enjoyment of life, enormous medical expenses, both past and future.

13. The additional designated plaintiff, Donald Savercool, has suffered/will continue to suffer the following: Including but not limited to, he has watched his wife suffer. He has suffered a loss of consortium and has endured much mental anguish. He has incurred, and will continue to incur, medical expenses and increased living and support expenses.

Plaintiff(s) reserve(s) the right to amend this Complaint to add allegations and claims against individuals or entities currently omitted (in light of the Court's order permitting a Master Complaint naming defendants affiliated with NECC and currently participating in mediation by December 20) and to add or amend allegations against Defendants named herein based, in part, on further discovery.

WHEREFORE, Plaintiff(s) demand(s) Judgment against Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just. Pursuant to Tenn. Code Ann. § 29-28-107,

Plaintiffs pray for damages in an amount not to exceed \$15,000,000.00 as set forth in Plaintiffs' Original Complaint.

SECOND COUNT

14. Plaintiff(s) re-allege and incorporate by reference each of the foregoing paragraphs as if set forth at length herein.

15. Plaintiff(s) assert(s) the following additional Causes of Action against Defendants: Plaintiffs incorporate all allegations and counts contained in Plaintiffs' Original Complaint found at Docket No. 1, together with all attachments thereto, if any, in the litigation styled Savercool v. Ameridose LLC, et al.; United States District Court, District of Massachusetts, 1:13-cv-12583-RWZ, (MDL No. 1:13-md-2419-RWZ) together with all prayers for relief stated therein.

16. Plaintiff Shirley Savercool suffered injuries as set forth in Paragraph 11 herein.

17. Plaintiff Shirley Savercool suffered damages as set forth in Paragraph 12 herein.

18. The additional designated plaintiff, Donald Savercool, has suffered/will continue to suffer the following: please see Paragraph 13 herein.

WHEREFORE, Plaintiff(s) demand(s) Judgment against Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just.

THIRD COUNT

19. Plaintiff(s) re-allege(s) and incorporate(s) by reference each of the foregoing paragraphs as if set forth at length herein.

20. Plaintiff(s) assert(s) the following additional Causes of Action against the Clinic Related Defendants, collectively for purposes of this count, the "Tennessee Defendants."

- i. Plaintiff played no role in selecting the supplier of the MPA that Defendant, Specialty Surgery Center, through its agents and employees, injected into her spine. Plaintiff relied exclusively upon Specialty Surgery Center, and its employees and agents, to make that selection.
- ii. Given the well-known dangers of bulk pharmacy compounding, the Tennessee Defendants ignored grave risks of foreseeable harm when they permitted Specialty Surgery Center to purchase injectable steroids from NECC in bulk and without individual prescriptions.
- iii. On information and belief, given the well-known dangers of bulk pharmacy compounding, the Tennessee Defendants ignored grave risks of foreseeable harm when they permitted Specialty Surgery Center to conspire with NECC in the creation of false paper trails intended to hide NECC's wrongful and intentional conduct from regulators.
- iv. On information and belief, the Tennessee Defendants stood in a special relationship with Plaintiff. By virtue of that special relationship, the Tennessee Defendants owed a duty to protect their patients, including Plaintiff, from foreseeable harm caused by NECC's intentional conduct. NECC engaged in numerous instances of intentional misconduct. That intentional misconduct included but is not limited to: (a) mass producing compounded medications and selling them in bulk in circumvention of the FDA system of regulating drug manufactures; (b) providing false information to government regulators; (c) mass producing compounded medications and shipping those medications to Tennessee without patient

specific prescriptions in violation of Massachusetts Board of Pharmacy Rules and Tenn. Code Ann. § 63-10-204(4); (d) enlisting the aid of its customers in creating false paper trails designed to hide its misconduct from government regulators; and/or (e) mass producing purportedly sterile injectable drugs under filthy conditions in violation of regulations promulgated by the Massachusetts Board of Registration in Pharmacy and found at 24 7 CMR 6.02(1).

- v. The Tennessee Defendants breached their duty to their patients, including Plaintiff, by failing to protect them from the foreseeable harm caused by NECC's intentional conduct.
- vi. As a direct and proximate result of the Tennessee Defendants' breach of their duties, Plaintiff suffered physical injuries.
- vii. Because the Tennessee Defendants owed Plaintiff a duty to protect her from NECC's conduct, the Tennessee Defendants' fault cannot be reduced by any fault attributable to NECC. Accordingly, the Tennessee Defendants are jointly and severally liable for all harm caused by NECC's conduct.

21. Plaintiff Shirley Savercool suffered injuries as set forth in Paragraph 11 herein.

22. Plaintiff Shirley Savercool suffered damages as set forth in Paragraph 12 herein.

23. The additional designated plaintiff, Donald Savercool, has suffered/will continue to suffer the following: please see Paragraph 13 herein.

WHEREFORE, Plaintiff(s) demand(s) Judgment against the Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just.

FOURTH COUNT

24. Plaintiff(s) re-allege(s) and incorporate(s) by reference each of the foregoing paragraphs as if set forth at length herein.

25. Plaintiff(s) assert(s) the following additional Causes of Action against Specialty Surgery Center, PLLC.

- i. Specialty Surgery Center was negligent in the manner in which it operated.
- ii. Specialty Surgery Center knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.
- iii. Specialty Surgery Center negligently:
 - a. operated in a manner which facilitated the procurement of injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;
 - b. failed to visit NECC's facilities before procuring spinal injection medicines from NECC;
 - c. failed to determine whether NECC had a history of recalling compounded medications before permitting procuring spinal injection medicines from that company;
 - d. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from NECC;
 - e. failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from NECC;
 - f. failed to keep abreast of the dangers of sterile compounding;

- g. failed to operate with reasonable and due care, including a complete failure to supervise its drug procurement practices reasonably;
 - h. failed to supervise adequately;
 - i. failed to exercise due and reasonable care in conducting financial and contracting operations;
 - j. procured compounded injectable steroids in bulk from NECC without using patient-specific individual prescriptions;
 - k. failed to adequately supervise and train the physicians, nurses, agents and employees who ordered MPA from NECC;
 - l. failed to implement or enforce policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;
 - h. facilitated or permitted the injection of steroids into Plaintiff's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;
 - m. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives; and
 - n. failed to promptly notify Plaintiff that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt treatment of her exposure to potential fungal infection.
- iv. The person or persons who decided to procure MPA from NECC were employees or agents of Specialty Surgery Center and were acting within the course and scope of their employment or agency. Accordingly, Specialty Surgery Center is liable for the consequences

of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

26. Plaintiff Shirley Savercool suffered injuries as set forth in Paragraph 11 herein.

27. Plaintiff Shirley Savercool suffered damages as set forth in Paragraph 12 herein.

28. The additional designated plaintiff, Donald Savercool, has suffered/will continue to suffer the following: please see Paragraph 13 herein.

**FIFTH COUNT - NEGLIGENCE
(AGAINST NEW DEFENDANT CALISHER AND ASSOCIATES)**

29. Calisher held itself out at all relevant times as a corporation with “expertise in the development and management of state-licensed, Medicare-certified and accredited ambulatory surgery centers, endoscopy centers, and other outpatient facilities. Calisher provided management services to SSC continuously from 2009 through 2013. Plaintiff did not know, and had no reasonable basis to knowing, of Calisher’s role in managing SSC until, at the earliest, August of 2014 when Calisher was identified in SSC’s initial disclosures as a company involved in managing SSC. Plaintiff did not know, and had no reasonable basis to know, of Calisher’s role in selecting NECC as a vendor or that SSC would rely on Calisher for help in selecting NECC as a vendor until it took the depositions of Dr. Lister and Jean Atkinson in February of 2015.

30. Calisher, Jean Atkinson, and others, acting in concert, selected New England Compounding Center (“NECC”) as the vendor of MPA to SSC, including the contaminated lots that caused injuries and deaths.

31. Calisher created the formulary that determined which drugs would be used by SSC.

32. Prior to ordering MPA from NECC, Jean Atkinson, Director of Nursing,

Circulator OR and endoscopy, Holding Area/PACU, of SSC, asked Calisher's approval for ordering MPA from NECC, a new vendor. According to Atkinson, if Calisher had refused to provide its approval, she would not have ordered MPA from NECC on behalf of SSC.

33. SSC relied upon Calisher and Atkinson to do appropriate due diligence into NECC, including its history and sterility practices.

34. Upon information and belief Calisher and Atkinson failed to perform adequate due diligence of NECC prior to SSC ordering MPA from NECC.

35. SSC relied, in part, on the Calisher's experience, information, and purported expertise in managing ambulatory surgery centers throughout the country.

36. Calisher and Atkinson were aware prior to SSC's purchase of MPA from NECC that NECC did not require a patient-specific prescription from SSC for each unit of MPA. Defendants also had knowledge that SSC provided a list of patient names to NECC at NECC's request, even though it was clear that the MPA would be used for patients other than those on the list, and some of the patients on the list would not receive MPA.

37. Calisher acted in concert with Atkinson and defendants, including SSC, in selecting, vetting, and purchasing subject MPA from NECC, which they sold, caused to be sold, and/or aided and abetted the selling of, to Plaintiff, causing injuries.

38. Calisher's decision, along with Atkinson, SSC, and others, to select and/or approve NECC as a supplier of purportedly sterile injectable steroids was negligent.

39. Calisher knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.

40. Calisher acting through its agents, employees, and representatives negligently and recklessly purchased or caused to be purchased contaminated MPA from NECC. Calisher failed

to conduct appropriate due diligence regarding NECC. Had they done so, any reasonable purchaser would have declined to purchase from NECC.

41. Calisher, acting in concert with other defendants, was negligent in its conduct, which fell below the applicable standard of care in at least the following ways:

- a. Procuring or causing to be procured injectable steroids from NECC, for the purpose of being injected into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;
- b. Failed to visit or otherwise inspect NECC's facilities before procuring spinal injection medicines from that company;
- c. Failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;
- d. Failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;
- e. Failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from that company;
- f. Failed to keep abreast of the dangers of sterile compounding;
- g. Purchased or caused to be purchased compounded injectable steroids in bulk from NECC without using patient-specific individual prescriptions;
- h. Failed to follow its own formulary that would have prevented the use of MPA compounded by NECC in epidural steroid injections;

- i. Failed to implement policies and procedures that would prevent the procurement of purportedly sterile injectable medications from and out-of-state compounding pharmacy with inadequate sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;
- j. Approved, facilitated, or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives.
- k. Sold, caused to be sold, and/or aided and abetted the selling of, contaminated steroids to Plaintiff, causing injuries.
- l. As a direct and proximate result of the negligent acts and omissions described above, Plaintiff suffered injuries and damages that would not have otherwise occurred. Agents, employees, and representatives of Calisher who approved or otherwise facilitated the procurement of MPA from NECC were acting within the course and scope of their employment or agency with Calisher. Accordingly, Calisher is responsible for the consequences of their agents, employees, and representatives pursuant to the doctrine of *respondeat superior*.

WHEREFORE, Plaintiff(s) demand(s) Judgment against the Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just.

**CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE
UNCONSTITUTIONAL AND VOID *AB INITIO***

42. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting “caps” in all Tennessee personal injury cases for non-economic damages and punitive damages.

Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiff's non-economic damages are purportedly capped at \$750,000, and their ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of \$500,000.

43. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiff's constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever . . . and shall forever remain inviolate." Therefore, Plaintiff requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void ab initio and of no force and effect.

44. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Amended Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiff is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

JURY DEMAND

Plaintiff(s) hereby demand(s) a trial by jury.

Date: 11/03/2015

Respectfully Submitted,

BRANSTETTER, STRANCH & JENNINGS PLLC

/s/ J. Gerard Stranch, IV

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CERTIFICATE OF SERVICE

I, J. Gerard Stranch, IV, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: November 3, 2015

/s/ J. Gerard Stranch, IV
J. Gerard Stranch, IV